

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2004/003917

International filing date (day/month/year)
15.09.2004

Priority date (day/month/year)
08.10.2003

International Patent Classification (IPC) or both national classification and IPC
A61B17/16

Applicant
DEPUY INTERNATIONAL LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/003917

Box No. II Priority

1. ☒ The following document has not been furnished:

- ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).
- ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

- 2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
 - 3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.
4. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 7

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 7

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/003917

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-6,8-14
	No: Claims	
Inventive step (IS)	Yes: Claims	14
	No: Claims	1-6,8-13
Industrial applicability (IA)	Yes: Claims	1-6,8-14
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and /or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

Re Item V.

- 1 The following documents are referred to in this communication:

D1 : US-B-6 475 221

D2 : DE-U-71 13 620

D3 : US-A-5 299 893

2 INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 1 does not involve an inventive step in the sense of Article 33(3)PCT.

- 2.1.1. Document D1, which is considered to represent the most relevant state of the art to the subject matter of claim 1, discloses (the references in parenthesis applying to this document):

A cutting tool (column 6, lines 16-19) for preparing a cavity in a bone for receiving a component of an orthopaedic joint prosthesis, in which the shape of the tool is based on a shell having a rotationally symmetrical outer surface, in which the external surface presents at least two outwardly directed cutting teeth (column 6, lines 49-63), arranged such that the net translational force on the tool in the plane which is perpendicular to the axis of rotation, resulting from the accumulated resistance of the teeth when rotated against a rotationally symmetrical cavity in which the tool is snug fit, is approximately balanced (column 10, lines 47-58).

- 2.1.2 The subject-matter of independent claim 1 differs from the disclosure of D1 in that :

The tool has at least one portion cut out from it, the cut out portion extending from the peripheral edge of the shell toward the pole of the shell, such that the tool has no more than one plane of symmetry passing through the axis of rotation,

- 2.1.3 The problem to be solved by the present invention may therefore be regarded as

Minimizing the effect of vibration due to the accumulation of bone debris inside the operation field.

- 2.1.4 In view of D2 the solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

A cut out portion (see claim 1; reference 4) is disclosed in D2 for preventing vibration (see description paragraph 2).

- 2.1.5 Therefore the features disclosed in D1 and D2 would be combined by the skilled person, without exercise of any inventive skills in order to solve the problem posed. The proposed solution in independent claim 1 thus cannot be considered inventive (Article 33(3) PCT).

3 DEPENDENT CLAIMS 2-6 AND 8-13

Dependent claims 2-13 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT).

- 3.2 Claim 3: Document D3 shows two balanced teeth (Article 33(3) PCT) (see figure 7; column 7, lines 18-22).
- 3.3 Claims 4-6: Document D1 shows three balanced and more than three balanced teeth.
- 3.4 Claim 8: D1 discloses at least one interrupted spiral (see figure 24; column 9, line 58 - column 10, line 21).
- 3.5 Claim 10: A bar is disclosed in D1 (reference 440; column 11, lines 3-9).
- 3.6 Claims 11-13: Document D2 discloses an upper sphere like part (see figure 1).

4 DEPENDENT CLAIM 14

Dependent claim 14 seems to be new and inventive (Article 33(2) and (3) PCT).

The subject-matter of claim 14 underlies the problem of augmenting the number of cutting teeth in combination with a sphere having a cutout portion while inhibiting the effect of vibration. As no balancing in the pole region is needed, the total surface in the pole region can be used for placement of cutting teeth.

5 The subject-matter of claims 1-6,8-14 is industrially applicable (Article 33(4) PCT).